

Introduction of a novel neonatal warming device in Malawi: an implementation science study

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Background: Neonatal hypothermia significantly contributes to infant morbidity and mortality in low-resource settings like Malawi. Kangaroo mother care (KMC) is essential but faces challenges in providing continuous thermal support. The Dream Warmer is a neonatal warming device that was developed to complement KMC. We studied its implementation outside a research environment.

Methods: Using an implementation science approach, we conducted a prospective interventional cohort study in two hospitals and four health centres in Malawi. Through audits and surveys, we assessed the effect of the Dream Warmer on neonatal hypothermia as well as healthcare provider (HCP) and parent attitudes regarding thermoregulation and related issues.

Results: The Dream Warmer raised no safety concerns and effectively treated hypothermia in 90% of uses. It was positively received by HCPs and parents, who reported it had a favourable effect on the care of small and sick newborns. Challenges identified included a scarcity of water and electricity, lack of availability of the device and HCPs forgetting to prepare it in advance of need or to use it when indicated. Feedback for future training was obtained. The Dream Warmer's strong safety and effectiveness performance is consistent with results from strict research studies. Training materials can be adapted to optimize integration into daily practice and provide educational content for parents.

Conclusions: The Dream Warmer is a safe and effective device to treat neonatal hypothermia, particularly when KMC is insufficient. We gained an understanding of how to optimize implementation through robust HCP and family education to help combat hypothermia.

Keywords: implementation science, KMC, LMIC, Malawi, neonatal hypothermia, newborn.

Background

Preterm birth is a major contributor to worldwide neonatal morbidity and mortality.^{1–4} Premature infants are prone to complications due to impaired respiration, feeding difficulties, infection risk and poor thermoregulation, making preterm birth a leading cause of mortality in children <5 y of age, accounting for about 18% of global deaths.^{2,5} Among the recommendations to improve outcomes for preterm infants, the World Health Organization (WHO) strongly advocates for kangaroo mother care (KMC), which has been proven to improve health.^{6,7} This intervention involves early, prolonged skin-to-skin contact and exclusive breastfeeding for preterm newborns weighing ≤ 2000 g.

The success of KMC relies on continuous provision of thermal support.⁸ Challenges like maternal pain and fatigue, interruptions and difficulty holding the infant can hinder the effectiveness of KMC.^{2,9} For infants who experience hypothermia despite KMC, the Every Newborn Counts 2 program recommends additional warming methods such as heat-producing wraps.^{10–12}

In Malawi, where complications of prematurity account for 37% of newborn deaths,¹³ the government has prioritized KMC for decades.^{2,14} Despite the widespread adoption of KMC, mothers still face challenges.¹⁴

Current low-cost alternatives to KMC and electric warmers include polyethylene wraps, bags, caps, light bulbs, hot water

bottles and hot mattresses. In the rural setting, hot coals, thermal boxes and room warmers are also employed.^{15–18} Each option has major limitations related to cost, effectiveness, safety, sanitation, portability and need for electricity.^{15,19–21}

In sub-Saharan Africa, a lack of resources for thermoregulation hampers efforts to reduce hypothermia-related neonatal deaths.¹ In response to this need, the Dream Warmer was developed as a neonatal warming mattress for low-resource settings.¹⁷ It is a skin-temperature mattress comprised of a specialized phase-change wax material that, once melted by submersion in boiling water, maintains a temperature of 37°C for approximately 6 h. A 40°C thermal indicator determines safety for initiation of use. Manual palpation of the mattress to assess ongoing warmth and softness determines termination of use, after which it is wiped down with standard cleanser and re-used hundreds of times. The Dream Warmer kit costs <US\$100 and includes the wax mattress, an insulating sleeve, thermos and backpack for portability and storage. It has been determined by the US Food and Drug Administration to be a ‘product’, not a ‘device’ and therefore is outside their purview for certification. It can supplement KMC when it is insufficient or provide an external heat source when mothers are unavailable for KMC. Its safety and effectiveness were validated in three prior trials.^{22–24} Our current study aims to assess its safety and effectiveness and understand attitudes about its use outside a strict research setting.

Methods

We conducted a prospective interventional one-arm, open-label, mixed-methods cohort study at Neno District Hospital, at a referral community hospital and at four health centres in rural Malawi. Neno District, in southwestern Malawi, has a population of 150 000.²⁵ It is a geographically challenging region with difficult access to health services. Since 2007, Partners In Health (PIH) has collaborated with the Malawi government to improve maternal and neonatal care in this district. In 2016, a small neonatal unit was established.^{16,26}

Our intervention was comprised of training sessions about neonatal hypothermia, followed by provision of the Dream Warmer. We collected data through a set of two audits and five surveys consisting of Likert-scale, multiple-choice and free-text questions.

Our aims were to evaluate the effect of the warmer on hypothermic newborns; assess whether there were any new benefits, barriers or safety concerns regarding the use of the warmer outside of a strict research setting; and capture the end user’s experience with the warmer.

Per the WHO,²⁷ we defined eutheria as an axillary temperature of 36.5–37.5°C. Temperatures below this were categorized as hypothermia and above as fever. Healthcare providers (HCPs) were medical doctors, registered nurses, nurse midwife technicians, community midwives (subset of nursing profession in Malawi), clinical officers and medical assistants.

Study staff obtained signed informed consent from parents who agreed to participate in the surveys. Consent was implied for HCPs who participated in trainings and surveys. Because the warmers were being used outside of a study protocol, based on

extensive safety and effectiveness data, we did not obtain consent for their use.

We used Stata/BE 17.0 (StataCorp, College Station, TX, USA) for our analysis of descriptive statistics. The details of our study design were structured around components of the RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) framework, a widely used model in implementation science.^{28,29} We structured the study design, methods and analysis around this framework to ensure evidence-based interventions were effectively translated and adapted for real-world applications (Table 1).

Reach

To reach relevant HCPs, we conducted trainings at Neno District Hospital, one referral community hospital and four referral health centres. Trainings covered the definition of hypothermia, dangers of neonatal hypothermia and provision of high-quality KMC complemented by the warmer. We provided a neonatal hypothermia management algorithm (appendix). It included use of the warmer for infants <2.5 kg/35 weeks’ gestation when KMC was not available and for infants who were hypothermic while receiving KMC. It was also recommended for use on the labour and delivery ward or on transport at the discretion of the healthcare team. The algorithm served only as a guideline, the actual use of the warmer was left to the discretion of the healthcare team. Our goal was to educate all the HCPs working the day the training was offered. We relied on a train-the-trainer approach to reach the rest of the HCPs.

To assess our reach of HCPs, we administered two surveys, the HCP Pre-Warmer Survey and the Training Survey. The study goal was to have all HCPs who took the training complete these two surveys.

The HCP Pre-Warmer Survey assessed HCPs’ knowledge of the definition of hypothermia and its associated morbidities and their confidence in preventing hypothermia, assisting with KMC and providing overall care for small and sick newborns. The Training Survey evaluated the effectiveness of the trainings and recommendations for improvement.

To reach the parents whose babies used the warmer, we administered a Parent Pre-Warmer Survey. This assessed parents’ attitudes towards KMC, breastfeeding, bonding and post-partum recovery; their understanding of the importance of preventing hypothermia; and their perception of their newborn’s growth. The study goal was to obtain at least 24 Parent Pre-Warmer Surveys.

Effectiveness

To evaluate the intervention’s effectiveness, we conducted a Warmer Use Audit, collecting information on the warmer’s safety, effectiveness and usability. The study goal was to complete 24 Warmer Use Audits.

Adoption

To establish adoption of our intervention through organizational support, our study coordinator secured collaboration within the local health system and oversaw the study. This individual served as a local thermoregulatory champion, assisting with training,

Table 1. RE-AIM components with data collection method, sample source, and size

RE-AIM component	Data collection method	Sample source and size
Reach	HCP Pre-Warmer Survey Training Survey Parent Pre-Warmer Survey	HCPs trained; all parents whose babies used the Dream Warmer; target of 24 Parent Pre-Warmer Surveys
Effectiveness	Warmer Use Audit	Target of 24 Warmer Use Audits
Adoption	Warmer Non-Use Audit Local thermoregulatory champion engagement	Up to 24 Non-Use Audits
Implementation	HCP Post-Warmer Survey Parent Post-Warmer Survey	HCPs and parents after intervention usage
Maintenance	Engagement with Malawi Ministry of Health	Aim of nationwide integration and scalability

supervising distribution of the warmers and monitoring many of the surveys and audits to optimize accurate data collection. He provided overall support for the project, acting as a liaison between the study team, hospital administration, local community and Malawi Ministry of Health.

To evaluate adoption of the warmer, we conducted a Warmer Non-Use Audit to understand why it was not used when indicated. The audit offered a series of reasons why an HCP did not use the warmer, including an option for open-ended answers. The study goal was to complete up to 24 Non-Use Audits.

Implementation

To ensure the proper implementation of the intervention, we conducted two surveys, the HCP Post-Warmer Survey and the Parent Post-Warmer Survey. These surveys were conducted at the district hospital only, and therefore we did not intend to exactly match individuals who completed the Pre-Warmer Surveys that were conducted at all of the study sites.

The HCP Post-Warmer Survey evaluated HCPs' perceptions of usability, preparation, safety and adoption of the warmer; the effect on KMC; and recommendations for improvement.

The Parent Post-Warmer Survey assessed parents' perception of the warmer's effectiveness, recommendations for improvement and its impact on KMC, breastfeeding, bonding and post-partum recovery.

Maintenance

To integrate the intervention for long-term maintenance, we engaged the Malawi Ministry of Health throughout the process, aiming to scale the intervention countrywide if it was well received in this local study.

Each component of the study had different participants. Parents were the participants for the parent surveys. HCPs were the participants for the HCP surveys and the training assessments. Newborns were the participants in use of the warmer. Inclusion criteria are described in the 'Reach' section. There were no exclusion criteria.

Table 2. Number of responses to surveys and audits

Survey/audit	Responses, n
Warmer Use Audit	20
Warmer Non-Use Audit	25
Training Survey	36
HCP Pre-Warmer Survey	67
HCP Post-Warmer Survey	22
Parent Pre-Warmer Survey	35
Parent Post-Warmer Survey	35

We did not conduct formal sample size calculations for this implementation science study. Rather, we provided our intervention to the two hospitals and four associated health centres because this is where PIH is present in-country. Within this context, we designed the number of surveys to balance the desire for information with the burden on study staff and parents, as well as the expectation to reach saturation in our qualitative responses based on previous qualitative research.²³

Results

The study ran from July 2022 to May 2023. The research team conducted six trainings, one each at the Neno District Hospital, the referral community hospital and the four health centres. We trained 67 HCPs (medical doctors [n=3], registered nurses [n=12], nurse midwife technicians [n=33], community midwives [n=4], clinical officers [n=14] and medical assistants [n=1]). We distributed 16 Dream Warmers: 10 to Neno District Hospital, 2 to the referral community hospital and 1 to each of the four health centres. The number of warmers distributed to the District Hospital was based on use at similar-sized hospitals during our previous clinical trials.²²⁻²⁴

We conducted the following surveys and audits (Table 2):

Table 3. HCP Pre-Warmer Survey results

HCP Pre-Warmer Survey, n=67	Accurately	Inaccurately			
Defined neonatal hypothermia, n (%)	23 (34)	44 (65)			
Listed at least one complication of hypothermia, n (%)	37 (55)	30 (45)			
	Very important	Important	Neutral	Unimportant	Very unimportant
Importance of euthermia, n (%)	55 (82)	6 (9)	6 (9%)	0	0
	Very confident	Confident	Neutral	Unconfident	Very unconfident
Confidence keeping small or sick newborns warm with KMC, n (%)	15 (22)	20 (30)	26 (39)	0	1 (1.5)
	Very fast	Fast	Neutral	Slow	Very slow
Perception of weight gain for small or sick newborns, n (%)	5 (7)	26 (39)	18 (27)	0	12

Reach

We obtained 67 HCP Pre-Warmer Surveys (Table 3). A minority accurately defined euthermia, while a majority described complications of hypothermia and regarded euthermia as important. Approximately half felt confident keeping small and sick newborns warm with KMC. There was a wide variation in the perception of rate of weight gain.

Thirty-six participants completed the Training Survey (data not shown, predominantly qualitative responses to free-text questions). All respondents reported the learning objectives were achieved. The session was considered helpful by all respondents, especially for its emphasis on preventing hypothermia, its hands-on demonstration, teaching preparation and use of the warmer.

Nineteen respondents offered suggestions to improve the trainings. These included more discussion on the warmer's relationship to KMC; more information on its operation, care and storage; more time and resources for practice; the opportunity to demonstrate competency; inclusion of a wider spectrum of HCPs; repetition of the training and regular refresher training.

Thirty-five Parent Pre-Warmer Surveys were completed, all by mothers (Table 4). All responded that they were providing KMC for their babies and thought it was important to keep their baby's temperature normal. The vast majority reported they felt confident in and enjoyed providing KMC and were confident in their milk supply. Because KMC is associated with improved lactation and breastfeeding, questions regarding milk supply were intended to ensure that the Dream Warmer did not interfere with this critical aspect of newborn care.

Effectiveness

Twenty Warmer Use Audits were completed (Table 5), all at Neno District Hospital where the study coordinator was based. In all 20, the mattress was reported to be prepared correctly. However, in only seven was it prepared in advance of need. The median body temperature rose from hypothermic (35.0°C [range 33.9–36.9°C]) at initiation of warmer use to eutermic (36.8°C [range 35.9–37.6°C]) during warmer use. Two patients remained hypothermic despite warmer use. One had a starting temperature of 35.0°C,

Table 4. Parent Pre-Warmer Survey results

Parent Pre-Warmer Survey	Yes, n (%)	Neutral, n (%)	No, n (%)
Have you been providing KMC for your baby?	35 (100)	0	0
Is it important to keep baby's temperature in normal range?	35 (100)	0	0
Do you enjoy providing KMC?	34 (97)	1 (3)	0
Do you feel confident providing warmth through KMC?	34 (97)	1 (3)	0
Do you feel confident in having an adequate milk supply?	34 (97)	1 (3)	0

a maximum temperature of 35.9°C, remained on the warmer for only 1 h 20 min and stopped warmer use because it was reported to have become cold. The second started at 34.6°C, also had a maximum temperature of 35.9°C, stayed on the warmer for 6 h 30 m and was removed because the warmer was reported to have become cold.

The warmer was used for a median duration of 6 h (range 1 h 20 min–7 h 50 min). In 12/20 audits, the indication for terminating warmer use was that it became cold. In the other eight, the mother requested to resume KMC. In two cases, the audits recorded pre-existing safety concerns (e.g. skin rash) prior to initiating the warmer. In one of these cases, there were ongoing safety concerns during/after warmer use. No further details were provided. No additional safety concerns were reported after warmer use.

The most common problems reported with use of the warmer were water scarcity and unavailability of the warmer. In an open-ended question about additional concerns regarding the warmer, one audit reported 'family concern not fully addressed', with no

Table 5. Warmer Use Audit results

Warmer Use Audit	Values
Mattress placed in thermos prior to adding boiled water, n (%)	20 (100)
Temperature indicator used correctly, n (%)	20 (100)
Mattress prepared in advance of need, n (%)	7 (35)
Average time to prepare the warmer when not ready in advance (minutes)	19.2 (range 12–25)
Median body temperature (°C) at start of warmer use	35.0 (range 33.9–36.9)
Median body temperature (°C) during warmer use	36.8 (range 35.9–37.6)
Median duration of warmer use	6 h (range 1 h 20 min–7 h 50 min)
Reasons for warmer discontinuation, n (%)	
Warmer became cold	12 (60)
Mother requested to resume KMC	8 (40)
Pre-existing safety concerns, n (%)	2 (10)
Ongoing safety concerns during/after warmer use, n (%)	1 (5)
Water scarce, n (%)	8 (40)
Warmer unavailable, n (%)	6 (30)
Family concerned, n (%)	1 (5)
Breakdown of a warmer component, n (%)	1 (5)

Table 6. Warmer Non-Use Audit results

Warmer Non-Use Audit (n=25)	Values, n (%)
Absence of electricity	7 (28)
Insufficient time to boil water	4 (16)
Warmer not prepared in advance	2 (8)
HCP forgot to use warmer	7 (28)
Family member declined to use warmer	3 (12)
No explanation	2 (8)

further details specified. Additionally, one reported a concern about breakdown of a component of the warmer, also not further specified.

Adoption

A total of 25 Warmer Non-Use Audits were completed (Table 6). Reasons for non-use included the absence of electricity, insufficient time to boil water, warmer not being prepared in advance of need, forgetting to use the warmer and family members declining warmer use.

Implementation

Twenty-two HCPs completed the HCP Post-Warmer Survey (Table 7). The vast majority found it easy to learn how to use; easy to prepare (including advanced preparation and use of the temperature indicator), use, and clean; effective at keeping babies warm; comfortable for the mother; facilitated HCP workflow and used when needed.

Thirty-five Parent Post-Warmer Surveys were completed (Table 8). The vast majority reported the warmer worked well to keep their baby warm and promoted their ability to provide KMC, breastfeed, bond with their baby, feel confident in their baby's outcome and recover after childbirth. All 35 reported the warmer looked safe and well-built.

Maintenance

Based on these study results, PIH Malawi is expanding use of the Dream Warmer by procuring two additional warmers for each of the district's eight referring health centres. The study team presented the warmer to the Malawi Ministry of Health at the Safe Motherhood National Technical Working Group in August 2022, where it was approved as a thermoregulatory option. Currently the Malawi Ministry of Health is considering the role of the warmer outside of use at PIH-associated hospitals and health centres. With more financial support to procure warmers, the MOH is ready to implement their use across the country.

Discussion

Adoption of a new practice can be systematically promoted within the context of clinical trials, with their strict study protocols and close oversight. In contrast, introducing a new practice without this level of support can be challenging.³⁰ As the Dream Warmer transitions from a phase of research and development to that of scale, it is important to understand the use and perception of the warmer in real-world settings.

Although our sample size was smaller than in our previous studies, the overall safety and effectiveness results were similar.^{22–24} Combining the results of our three previous trials, the warmer was used 1074 times with no adverse events or instances when it was prepared, used or cleaned incorrectly. Of the 826 infants who were hypothermic prior to warmer use, 738 (89%) became eutermic. Of the 248 infants who were low birthweight and KMC was not available, 245 (99%) remained eutermic. There was a 10% rate of fever, which compared favourably with the 12% rate in patients not using the warmer.

In our current study in Malawi, the safety and effectiveness data that we collected were a subset of the data we collected in our previous trials, as this implementation science study had limited on-site study oversight and no formal study protocol. We collected data on safety concerns during warmer use, including rashes or burns. We collected starting and subsequent temperatures while on the warmer to assess the effectiveness of the warmer to increase infants' temperatures. There were two cases of pre-existing safety conditions, one of which appeared to resolve during warmer use, but one that remained after use. Our effectiveness data showed that all patients experienced an

Table 7. HCP Post-Warmer Survey results

HCP Post-Warmer Survey (n=22)	Very easy	Easy	Neutral	Difficult	Very difficult
Preparing the warmer, n (%)	3 (13)	13 (59)	4 (18)	2 (9)	0
Preparing the warmer in advance for use when needed, n (%)	1 (4.5)	10 (45)	11 (50)	0	0
Using the temperature indicator to determine if the warmer is safe to use, n (%)	2 (9)	17 (77)	1 (4.5)	2 (9)	0
Learning how to use the warmer, n (%)	10 (45)	7 (32)	3 (13)	2 (9)	0
Cleaning the warmer, n (%)	0	15 (68)	7 (32)	0	0
	Very effective	Effective	Neutral	Ineffective	Very ineffective
Performance of warmer to keep baby warm, n (%)	7 (32)	12 (55)	3 (13)	0	0
	Very comfortable	Comfortable	Neutral	Uncomfortable	Very uncomfortable
Comfort of mothers using the warmer as additional heat source while doing KMC, n (%)	3 (13)	11 (50)	8 (36)	0	0
	Much easier	Easier	Neutral	Harder	Much harder
Impact of warmer use on performing other duties required during shift, n (%)	3 (13)	11 (50)	6 (27)	2 (9)	0
	Never	Almost never	Neutral	Often	Very Often
Occurrence of hypothermia without KMC or other heat sources, and no infant warmer provided, n (%)	5 (23)	8 (36)	6 (27)	3 (13)	0

increase in temperature on the warmer; 90% either attained or maintained eutheria and none developed a fever. Although we did not specifically collect data on sufficiency of the 10 warmers at the hospital facility, on-site study staff report they did not run out of warmers; the comment 'warmer unavailable' referred to it not being prepared in advance, not that there were an insufficient number of warmers.

One warmer was reported to retain its warmth for only 1 h 20 min. This may be because it had been prepared too far in advance and was already cooling down before use. It could also have been due to misinterpretation of when the warmer had completely cooled. One warmer was reported to show signs of breakdown; these were research prototypes and subsequent commercially available Dream Warmers are made with a more robust plastic and sealing technique.

Our Warmer Non-Use Audit revealed a wide variety of reasons the warmer was not used when indicated. These data most directly addressed issues of how warmer use changed outside a strict study protocol. In 28% of audits, the HCP forgot to use the warmer. This speaks to the difficulty of introducing a new practice in a busy neonatal ward.³⁰ A total of 64% of HCPs said the warmer facilitated workflow. Twenty-eight percent cited non-use due to the absence of electricity and 16% cited insufficient time to boil water. Both of these responses underline the importance of preparing the warmer in advance of need, taking advantage of

when electricity is working. Twelve percent cited a family member declined use of the warmer, raising the important issue of family education in addition to HCP training, which has been our primary focus. Empowerment of mothers to advocate for thermoregulation on behalf of their babies is a key strategy to combat hypothermia. Because of the simplicity of providing KMC and the Dream Warmer, thermoregulation lends itself to family integrated care.³¹

The HCP Pre-Warmer Survey identified knowledge gaps regarding the definition of eutheria and a lack of confidence in mothers' ability to keep babies warm with KMC. The Training Survey highlighted the overall strength of our educational materials, including hands-on practice opportunities, but clarified the need for more competency-based training and refresher courses. This feedback will be instrumental in expanding programs to new personnel and locations, ensuring we deliver comprehensive, effective training as we continue to scale.

As in our previous research, we again found that HCPs do not consistently prepare the warmer in advance of need.²³ Although no respondents in the HCP Post Warmer Survey reported it was difficult to prepare in advance, only 35% actually did this according to the Warmer Use Audit. The reasons behind this challenge are likely multifactorial, including inconsistent electricity, water scarcity and workflow habits. We are investigating potential use

Table 8. Parent Post-Warmer Survey results

Parent Post-Warmer Survey (n=35)				
The warmer:	Very well	Well	Neutral	Very poorly
Works well to keep my baby warm, n (%)	1 (3)	31 (89)	3 (8)	0
	Strongly promoted	Promoted	Neutral	Strongly discouraged
Promotes my ability to provide KMC, n (%)	1 (3)	33 (94)	1 (3)	0
Promotes my ability to breastfeed, n (%)	2 (6)	32 (91)	1 (3)	0
Promotes bonding with my baby, n (%)	1 (3)	33 (94)	1 (3)	0
Promotes confidence that my baby will survive and thrive, n (%)	5 (14)	30 (86)	0	0
Promotes my recovery after childbirth, n (%)	2 (6)	33 (94)	0	0
	Yes	No		
Looks safe, n (%)	35 (100)	0		
Looks well-built, n (%)	35 (100)	0		

of a towel-warmer oven to heat the warmers in settings with intermittent electricity but limited water. In a similar implementation science study of the warmer in Chiapas, Mexico (manuscript in preparation), it was prepared in advance in 84% of uses. This Mexican site had more consistent electricity, no concerns regarding water supply and had Dream Warmer champions who influenced workflow habits by consistently encouraging advanced preparation.

The Parent Pre-Warmer and Post-Warmer Surveys showed overall positive maternal attitudes towards KMC that were not eroded by introduction of the warmer. In 40% of Warmer Use Audits, mothers requested to terminate warmer use in order to resume KMC. This resumption of KMC prior to the expected 6 h of warmer use suggests that it does not dissuade mothers from providing KMC.

Our study has several limitations. We were only able to obtain 20 of our goal of 24 Warmer Use Audits. These audits were only obtained at the District Hospital because health centres transport all hypothermic newborns to the hospital and therefore had only limited experience with use of the warmer. We did not have resources to collect data on rates of KMC or clinical outcomes, therefore we cannot assess the effect of introducing the warmer in these settings. The overwhelmingly positive responses reported in the Parent Surveys raise the possibility of survey bias,³² with mothers feeling pressure to avoid the perception of complaining. Performing the parent surveys after hospital discharge could have minimized this effect, but was not feasible in the context of this study design.

Conclusions

Neonatal hypothermia remains a recalcitrant problem plaguing neonatal survival and outcomes.⁵ The Dream Warmer was developed to complement KMC, providing external heat to anyone, anywhere. As recommended in the Every Newborn Counts 2 program, it is a heat-producing wrap that provides an additional heat source when KMC is insufficient despite optimizing the thermoregulatory environment.¹⁰ In this implementation science study, we learned that the Dream Warmer continues with the

same safety and effectiveness track record as reported with its use in strict research contexts. The major contributors to non-use of the warmer when indicated relate to lack of integration into daily practice. Stressing adverse consequences of hypothermia and identifying local thermoregulatory champions are strategies that have been proven effective elsewhere.³³ Although rare, parents' concern about use of the warmer raises the important issue of family education. Neonatal hypothermia remains a common yet preventable contributor to morbidity and mortality in low-resource settings. Implementing effective strategies to prevent and treat hypothermia is critical to optimizing neonatal outcomes.

Authors' contributions: MGM contributed to the study's development and participated in data collection, manuscript preparation, interpretation of data and provided critical revisions to the manuscript. AFG was involved in the study's development, data collection, manuscript preparation, data interpretation and assisted in the critical revision of the manuscript. LN actively contributed to the study's development, data collection, manuscript preparation and data interpretation and assisted in the critical revision of the manuscript. BLM was involved in the study's development, data collection and manuscript preparation and participated in the critical revision of the manuscript. IM played a key role in the study's development and data collection and contributed to the critical revision of the manuscript. FM contributed to the study's development, data collection, manuscript preparation and interpretation of data and participated in the critical revision of the manuscript. SK engaged in the study's development, data collection, manuscript preparation and data interpretation and contributed to the critical revision of the manuscript. AH participated in the study's conceptualization and oversaw the work of all contributing authors; was involved in the study's development, data collection, manuscript preparation and data interpretation; and played a key role in the critical revision of the manuscript. All authors have read and approved the final manuscript. They take responsibility for the accuracy and integrity of the work and agree that the manuscript represents valid research. They confirm that the manuscript has not been published or is under consideration for publication elsewhere.

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Ethical approval: The Institutional Review Board at Boston Children's Hospital and the National Health Sciences Research Committee of Malawi (protocol 20/10/1216) approved the study.

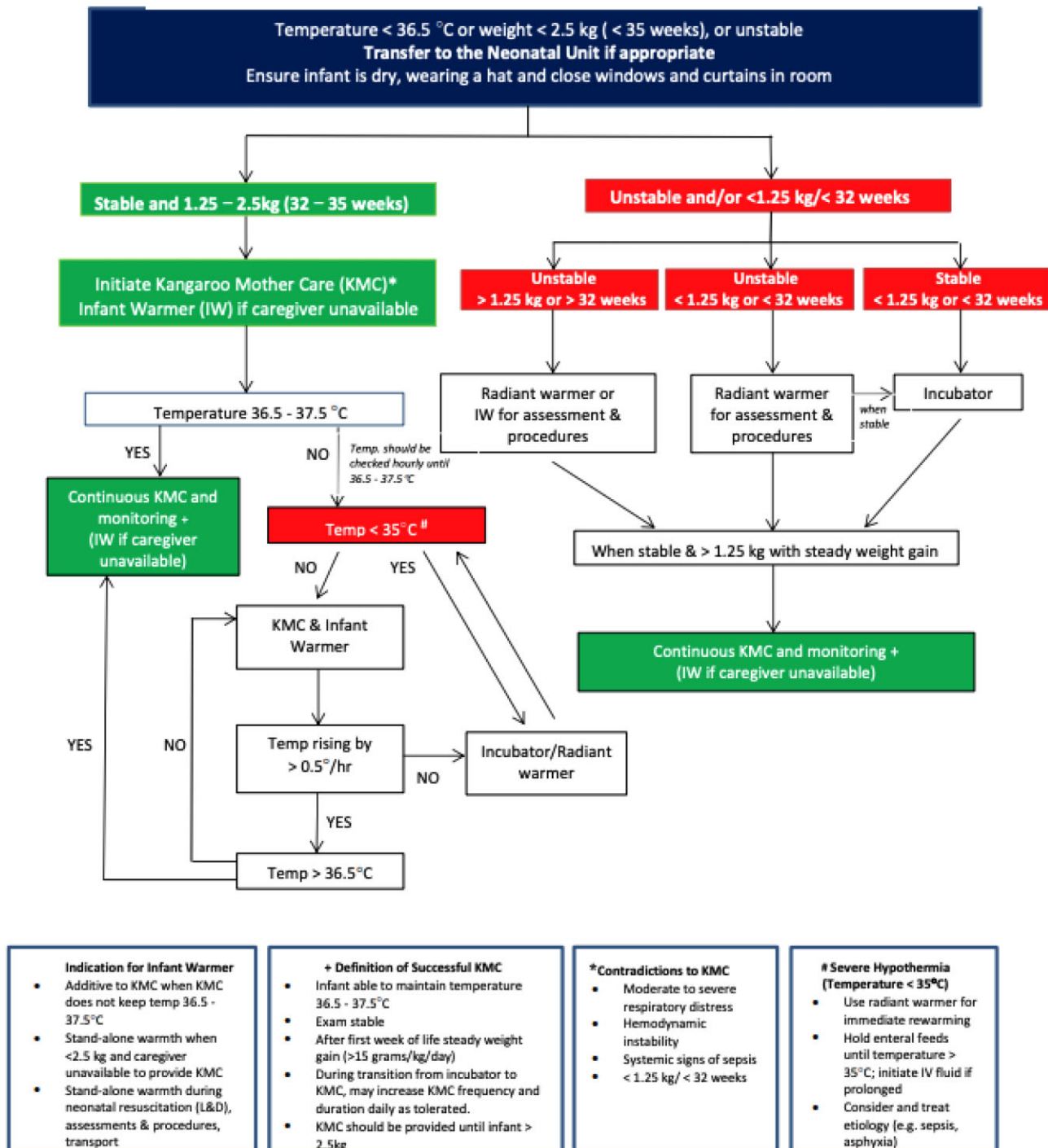
Data availability: Any interested reader may contact us directly for a link to our RedCap Database.

References

- Brambilla Pisoni G, Gaulis C, Suter S, et al. Ending neonatal deaths from hypothermia in sub-Saharan Africa: call for essential technologies tailored to the context. *Front Public Health*. 2022;10:945181.
- Chavula K, Guenther T, Valsangkar B, et al. Improving skin-to-skin practice for babies in kangaroo mother care in Malawi through the use of a customized baby wrap: a randomized control trial. *PLoS One*. 2020;15(3):e0229720.
- Delanaud S, Gossart L, Leclercq M, et al. Use of a novel mathematical model to assess the effectiveness of skin-to-skin care for the prevention of hypothermia in low-birth-weight neonates. *Appl Sci*. 2023;13(7):4412.
- Esteves JS, de Sá RAM, de Carvalho PRN, et al. Neonatal outcome in women with preterm premature rupture of membranes (PPROM) between 18 and 26 weeks. *J Matern Fetal Neonatal Med*. 2016;29(7):1108–12.
- Lunze K, Bloom DE, Jamison DT, et al. The global burden of neonatal hypothermia: systematic review of a major challenge for newborn survival. *BMC Med*. 2013;11:24.
- World Health Organization. WHO recommendations on interventions to improve preterm birth outcomes. Geneva: World Health Organization; 2015.
- Conde-Agudelo A, Díaz-Rossello JL. Kangaroo mother care to reduce morbidity and mortality in low birthweight infants. *Cochrane Database Syst Rev*. 2016;8:CD002771
- Chapak N, Ruiz JG, Zupan J, et al. Kangaroo mother care: 25 years after. *Acta Paediatr*. 2005;94(5):514–22.
- Mathias CT, Mianda S, Ohdihambo JN, et al. Facilitating factors and barriers to kangaroo mother care utilization in low- and middle-income countries: a scoping review. *Afr J Prim Health Care Fam Med*. 2021;13(1):2856.
- World Health Organization. Every Newborn Counts 2: action plan. Geneva: World Health Organization; 2021.
- Travers CP, Ramani M, Gentle SJ, et al. Early skin-to-skin care with a polyethylene bag for neonatal hypothermia: a randomized clinical trial. *J Pediatr*. 2021;231:55–60.e1.
- Komakech H, Lubogo D, Nabiwemba E, et al. Essential newborn care practices and determinants amongst mothers of infants aged 0–6 months in refugee settlements, Adjumani district, West Nile, Uganda. *PLoS One*. 2020;15(4):e0231970.
- Fottrell E, Osrin D, Alcock G, et al. Cause-specific neonatal mortality: analysis of 3772 neonatal deaths in Nepal, Bangladesh, Malawi and India. *Arch Dis Child Fetal Neonatal Ed*. 2015;100(5):F439–47.
- Lydon MM, Lweshya V, Likomwa D, et al. Re-envisioning kangaroo mother care implementation through a socioecological model: lessons from Malawi. *Glob Health Sci Pract*. 2022;10(4):e2100727.
- Ahmed S, Mitra SN, Chowdhury AMR, et al. Community kangaroo mother care: implementation potential for neonatal survival and health in very low income settings. *J Perinatol*. 2011;31(5):361–7.
- Bhat SR, Meng NF, Kumar K, et al. Keeping babies warm: a non-inferiority trial of a conductive thermal mattress. *Arch Dis Child Fetal Neonatal Ed*. 2015;100(4):309–12.
- McCall EM, Alderdice F, Halliday HL, et al. Interventions to prevent hypothermia at birth in preterm and/or low birthweight infants. *Cochrane Database Syst Rev*. 2010;3:CD004210.
- Carmichael A, McCullough S, Kempley ST. Critical dependence of acetate thermal mattress on gel activation temperature. *Arch Dis Child Fetal Neonatal Ed*. 2007;92(1):F44–5.
- Gupta R, Patel R, Murty N, et al. Developing sustainable global health technologies: insight from an initiative to address neonatal hypothermia. *J Public Health Policy*. 2015;36(1):24–40.
- PATH. Newborn thermal care devices: establishing a value proposition for low-resource settings. 2009. Available from: https://www.path.org/publications/files/TS_newborn_thermal_rpt.pdf [accessed 5 May 2017].
- Thairu L, Wirth M, Lunze K. Innovative newborn health technology for resource-limited environments. *Trop Med Int Health*. 2013;18(1):117–28.
- Nahimana E, May L, Gadgil A, et al. A low cost, re-usable electricity-free infant warmer: evaluation of safety, effectiveness and feasibility. *Public Health Action*. 2018;8(4):211–7.
- May L, Nshimiyiro A, Kubwimana M, et al. Performance of a nonelectric infant warmer in Rwandan health centers. *Glob Pediatr Health*. 2019;6:2333794X19884820.
- Uwamariya J, Mazimpaka C, May L, et al. Safety and effectiveness of a non-electric infant warmer for hypothermia in Rwanda: a cluster-randomized stepped-wedge trial. *EclinicalMedicine*. 2021;34:100842.
- National Statistical Office of Malawi. Malawi population and housing census: main report. Zomba, Malawi: National Statistical Office; 2018.
- Mhango J, Fisher A, Connolly E, et al. Lessons learned in creating a neonatal nursery at a district hospital in rural Malawi. *Ann Glob Health*. 2017;83(1):18–58.
- World Health Organization. Thermal protection of the newborn: a practical guide. Geneva: World Health Organization; 2015.
- Glasgow RE, Harden SM, Gaglio B, et al. RE-AIM planning and evaluation framework: adapting to new science and practice with a 20-year review. *Front Public Health*. 2019;7:64.
- Grol R, Grimshaw J. From best evidence to best practice: effective implementation of change in patients' care. *Lancet*. 2003;362(9391):1225–30.
- Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. *Implement Sci*. 2009;4:50.
- Janvier A, Asaad M-A, Reichherzer M, et al. The ethics of family integrated care in the NICU: Improving care for families without causing harm. *Semin Perinatol*. 2022;46(3):151528.
- Bowling A. Mode of questionnaire administration can have serious effects on data quality. *J Public Health (Oxf)*. 2005;27(3):281–91.
- Amelia T, Pratomo H, Adisasmita AC, et al. Feasibility of kangaroo mother care (KMC) implementation in Depok City, Indonesia. *Glob Pediatr Health*. 2021;8:2333794X211012390.

Appendix

Hypothermia Management of Newborns in Setting with Incubators/Radiant Warmers



Indication for Infant Warmer

- Additive to KMC when KMC does not keep temp 36.5 - 37.5°C
- Stand-alone warmth when <2.5 kg and caregiver unavailable to provide KMC
- Stand-alone warmth during neonatal resuscitation (L&D), assessments & procedures, transport

+ Definition of Successful KMC

- Infant able to maintain temperature 36.5 - 37.5°C
- Exam stable
- After first week of life steady weight gain (>15 grams/kg/day)
- During transition from incubator to KMC, may increase KMC frequency and duration daily as tolerated.
- KMC should be provided until infant > 2.5kg

***Contradictions to KMC**

- Moderate to severe respiratory distress
- Hemodynamic instability
- Systemic signs of sepsis
- < 1.25 kg/< 32 weeks

Severe Hypothermia (Temperature < 35°C)

- Use radiant warmer for immediate rewarming
- Hold enteral feeds until temperature > 35°C; initiate IV fluid if prolonged
- Consider and treat etiology (e.g. sepsis, asphyxia)

Hypothermia Management of Newborns in Setting without Incubators/Radiant Warmers

